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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/688,672 | 10/10/2000 | Yasir Skciky | 014058-009041US | 2671 |

20350 7590 05/13/2004

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EXAMINER

SWARTZ, RODNEY P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1645 | |

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------|-------------------------|---------------------|--|
| Advisory Action | Application No. | Applicant(s) | |
| | 09/688,672 | SKEIKY ET AL. | |
| | Examiner | Art Unit | |
| | Rodney P. Swartz, Ph.D. | 1645 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19March2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires 3 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. The proposed amendment(s) will not be entered because:

- (a) they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) they raise the issue of new matter (see Note below);
- (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached Detailed Action.

3. Applicant's reply has overcome the following rejection(s): _____.

4. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1-27, 105-115.

Claim(s) withdrawn from consideration: _____.

8. The drawing correction filed on _____ is a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. Other: _____.

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 19March2004, is acknowledged. The amendment will not be entered for the reason put forth below.

The examiner notes that the claim 110 is listed as being cancelled, but the remarks section does not indicate the cancellation. A telephone message from Annette S. Parent, Reg. No. 42, 058, received 27April2004 confirmed that claim 110 is to be cancelled.

Applicants propose cancellation of claims 9 and 110 and amendment of claim 1, 4, 7, 10, 12, 15, 18, 22, 25, 27, 105, 107, 109, 111, 112, and 114.

Reason for Nonentry

2. The proposed amendment cancels claim 9 and amends claim 10 to become dependent from claim 7. However, the proposed amendment of claim 10 would render the claim identical to claim 8, and thus raise a new issue under 35 U.S.C. 112, because both claims would read "The composition of claim 7, wherein the antigens are covalently linked, thereby forming a fusion polypeptide."

Remaining Rejection

3. In order to expedite the prosecution of the application, the examiner has reviewed the outstanding rejection in relationship to the proposed amendments.

4. The rejection of claims 9 and 110 under 35 U.S.C. 112, first paragraph, scope of enablement for immunogenic fragments or fusion products of immunogenic fragments, would be moot in light of the proposed cancellation of the claims.

5. The rejection of claims 1-3, 11-17, 105-109, and 111-115 under 35 U.S.C. 112, first paragraph, scope of enablement for immunogenic fragments or fusion products of

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immunogenic fragments, would be withdrawn in light of the proposed amendments of the claims.

6. The rejection of claims 4-6 and 18-27 under 35 U.S.C. 112, first paragraph, scope of enablement for immunogenic fragments or fusion products of immunogenic fragments, would be maintained following the proposed amendments of the claims.

The proposed amendment of claim 4 does delete the phrase "or an immunogenic fragment thereof" in lines 2 and 3, but the phrase "Tb38-1 antigen or an immunogenic fragment thereof" remains in line 3. Thus, the rejection would be maintained for the reasons put forth in the original rejection.

Conclusion

7. The amendment of 19 March 2004 will not be entered because it raises new issues, see above.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

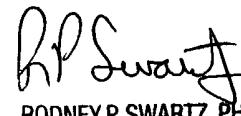
If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

May 4, 2004